Arguments/Remarks

Applicant has carefully reviewed and considered the explanation of the 2/20/07 Advisory Action and offers the following remarks. Applicants further gratefully acknowledge that the earlier 102 rejections have been withdrawn.

The claims have been amended as shown above. Presently amended claims are claims 1, 13, and 16. Claims 12 and 14 have been cancelled. Currently pending claims are claims 1-11, 13, 15-17. Applicant has added the phrase "olive vegetation water" to claims 1, 13 and 16. This phrase is supported in the specification in paragraph 0022. Applicant offers the following remarks regarding the Advisory Action:

Objection to the Claims

The Advisory Action objected to method claim 15 depending from composition claim 3. The undersigned regrets the typographical error. The dependency has been corrected to independent method claim 13 as indicated above. Therefore, this objection may be considered moot.

35 USC §112, First Paragraph, Written Description

The Advisory Action rejected claims 13 and 16 under paragraph 1 for lack of written description of "the entire genus of metabolic disorders of glucose metabolism" (claim 13) or metabolic disorders of glucose utilization (claim 16). The Advisory Action also considered the phrase in claim 13 to be redundant and not delineating what disorders are encompassed.

In contrast, a previous Office Action noted that three examples pertain to the use of a diabetic experimental rat and the administration of a composition falling within the scope of that claimed, which encompass "metabolic disorders of glucose utilization." And in response, Applicant amended the language in claims 13 and 16 to reflect such "metabolic disorders."

In further consideration of both Actions, Applicant has amended claim 13 to state "glucose utilization." Therefore, Applicant believes that this ground for rejection may be withdrawn. If this is not the case, perhaps a teleconference would be beneficial.

35 USC § 103

I. The Office Action rejected claims 1-6 and 8 as unpatentable over Crandall in light of Saija, and further in view of Cavazza (WO 00/11968).

Applicant has amended claim 1 to "olive vegetation water polyphenols". The Crandall reference only mentions olive oil, not olive vegetation water. The Saija reference does not discuss the composition of olive vegetation water, just olives and olive oil. Saija tested only pure hydroxytyrosol and oleuropein. The Saija reference does not teach or suggest hydroxytyrosol in a mixture of olive vegetation water polyphenols to improve the antioxidant status. Therefore, the combination of references cannot be relied upon to teach the combination of carnitine and olive vegetation water hydroxytyrosol-containing polyphenols. Therefore, this ground for rejection should be withdrawn.

II. The Office Action rejected claims Claims 1-11, 13 and 15-17 as unpatentable over Cavazza (USPN 6,365,622) or Cavazza (WO 00/11968) in view of Saija alone and cited to reasons of record at pages 17-20 of the previous Office Action. To recap, the Cavazza patent was derived from the PCT application of which the second Cavazza reference is the publication. Cavazza discloses the use of carnitine and lipoic acid. In this instance, Saija is applied separately for its teachings of the anti-oxidant effects of oleuropein and hydroxytyrosol.

Applicant has amended claims 1, 13 and 16 to claim olive vegetation water polyphenols. Cavazza also teaches that carnitine is a natural constituent of animal systems and exerts "stabilizing effects on cellular phospholipid membranes." (Col. 1, lines 44-45) Cavazza teaches with regard to lipoic acid, another compound present in animal systems, that it "performs an important

regulatory function on carbohydrate metabolism and insulin activity" (Col. 2, lines 31-33) and "an antioxidant effect [that is] either direct or indirect, via restoration of glutathione and ascorbic acid concentrations." (Col. 2, lines 59-61) Lipoic acid may work by inhibiting "the activation of the nuclear transcription factor (NF-kB) by reactive oxygen species (ROS), thus, in turn, inhibiting the associated cascade of neurotoxic cytotoxic factors." (Col. 3, lines 6-9) Cavazza states (Cols. 3-4) the following: "Surprisingly it has been found that a composition comprising as its characterizing components a combination of (a) acetyl L-carnitine or a pharmacologically acceptable salts thereof, and (b) α-lipoic acid..." While Cavazza teaches that various forms of carnitine are usable in the invention, it does not provide in any way for addition, replacement or substitution of lipoic acid. In fact, Cavazza attributes other advantages to lipoic acid which appear to be separate from the antioxidant property, which could contribute to the synergistic effect of lipoic acid with carnitine, including regulation of glucose utilization acting as a coenzyme in the oxidative decarbohydroxylation of pyruvate and other α-ketoacids and of insulin activity, and inhibition of aldose reductase activated by hyperglycemia (Col. 2, lines 40-65). Thus, to obtain a similar effect with carnitines, one of ordinary skill in the art would search for not just any antioxidant (of the numerous ones available), but one regulating glucose utilization, etc.

There is no reason in the art to assume that hydroxytyrosol would in combination or as substitute provide the same "synergistic" effect as lipoic acid. In fact, a synergistic effect indicates abnormal effect(s) not routinely found. Therefore, a routine substitution of any antioxidant would not be expected to have the same effect. Also, the claims cover a mixture of olive vegetation water polyphenols, which is not disclosed in Saija. Therefore, it is believed that this ground for rejection can be withdrawn.

Therefore, Applicant believes that a *prima facie* case of obviousness has not been proved and requests that the rejection be withdrawn.

Judicially Created Obviousness Double Patenting

The Office Action stated that the claims are obvious over the inventor's four prior patents (6197308; 6416808; 6165475 and 6936287). Upon allowance of any claim, Applicant agrees to execute terminal disclaimers for these patents.

CONCLUSION

Applicant believes that all grounds for rejection have been addressed and overcome. A notice of allowance is respectfully requested. If it would further the prosecution of this application or there is a need for any clarification, the Examiner is requested to telephone at 480-344-7745 the undersigned to reach agreement and disposal of this case.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being transmitted electronically on this 7 day of December, 2007

Chris Dohrwardt
Name

Signature